APPEAL BRIEF UNDER 37 C.F.R. § 41.37

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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Eric G. Lovett et al. Examiner: Kennedy Schaetzle

Serial No.: 09/970,146 Group Art Unit: 3766

Filed: October 02, 2001 Docket: 279.262US1

For: MEDICAL DEVICE HAVING RHEOMETRIC MATERIALS AND METHOD THEREFOR

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Appeal Brief is presented in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on February 6, 2006, from the Final Rejection of claims 1, 3-10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69 of the above-identified application, as set forth in the Final Office Action dated October 5, 2005.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of 500.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, CARDIAC PACEMAKERS, INC..

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals, interferences or judicial proceedings known to Appellants' Representatives which will directly affect, be directly affected by, or have a bearing on the Board's decision in the pending appeal.

3. STATUS OF THE CLAIMS

Claims 2, 11, 15, 17-20, 24, 25, 27, 30-32 and 34-37 are withdrawn. Claims 38-57 are canceled. Claims 1, 3-10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69 are rejected and are the subject of this Appeal (see Claims Appendix). Claims 1, 3-10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69 were rejected in the Final Office Action (hereinafter "the Final Office Action") dated October 5, 2005.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated October 5, 2005. The claims listed in the Claims Appendix reflect the claims as they currently exist.

5. SUMMARY OF CLAIMED SUBJECT MATTER

The subject matter is directed to a medical device including a lead assembly having rheometric material that contracts or stiffens with the application of electrical current. The rheometric material facilitates positioning of the lead assembly within the vasculature and the heart with a minimum of invasive procedures. This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellants refer to the appended claims and their legal equivalents for a complete statement of the invention.

a. Claim 1

The medical device includes a device body, such as lead body 115 shown, for example, in Figure 1. Specification page 10, lines 13-19. The lead body extends from a proximal end to a distal end (e.g., distal end 102 and proximal end 104 shown in Figure 1) and has an intermediate portion 105 therebetween. Specification page 10, lines 3-4. Additional examples of lead bodies 310, 410 and 510 are shown in Figures 4, 5 and 7, respectively. Specification page 13, lines 19-21; page 15, lines 5-15; and page 17, lines 6-19. In another option, the device body includes a guide catheter 600 shown, for instance in Figure 11. Specification page 21, lines 3-18. The medical device includes an electrode, such as electrode assembly 120, used to stiffen the device body (described below), deliver electrical stimulation to tissues and sense electrical activity in tissues. See for instance, Figures 2, and specification page 11, lines 1-9; page 12, lines 1-13; and page 13, lines 11-18. Additional example of electrodes 323, 423 and 523 are shown in Figures 4, 5 and 7, respectively. Specification page 13, line 28 to page 14, line 3; page 15, lines 15-18; and page 17, lines 20-23. Further, the medical device includes rheometric material electrically coupled with the at least one electrode, such as electrically active polymer 122 shown in one option, in Figure 2. Specification page 11, lines 10-28. Additional examples of rheometric material, such as strips 210; assemblies 320, 420, 520; and electroactive material 618, 714 are shown in Figures 4, 5, 6, 7, 12 and 19, respectively. Specification page 12, line 14 to page 13, line 10; page 13, lines 24-28;

page 14, line 4 to page 15, line 4; page 15, line 19 to page 17, line 5; page 17, line 24 to page 19, line 21; page 21, line 19 to page 22, line 10; and page 22, line 15 to page 25, line 26.

b. Claim 7

The device body, such as the lead body 115, is configured for coupling with a pulse generator 109, as shown in Figure 1. Specification page 10, lines 3-19.

c. Claim 9

The medical device includes a device body, such as lead body 115 shown, for example, in Figure 1. Specification page 10, lines 13-19. The lead body extends from a proximal end to a distal end (e.g., distal end 102 and proximal end 104 shown in Figure 1) and has an intermediate portion 105 therebetween. Specification page 10, lines 3-4. Additional examples of lead bodies 310, 410 and 510 are shown in Figures 4, 5 and 7, respectively. Specification page 13, lines 19-21; page 15, lines 5-15; and page 17, lines 6-19. In another option, the device body includes a guide catheter 600 shown, for instance in Figure 11. Specification page 21, lines 3-18. The medical device includes an electrode, such as electrode assembly 120, used to stiffen the device body (described below), deliver electrical stimulation to tissues and sense electrical activity in tissues. See for instance, Figures 2, and specification page 11, lines 1-9; page 12, lines 1-13; and page 13, lines 11-18. Additional example of electrodes 323, 423 and 523 are shown in Figures 4, 5 and 7, respectively. Specification page 13, line 28 to page 14, line 3; page 15, lines 15-18; and page 17, lines 20-23. Further, the medical device includes rheometric material electrically coupled with the at least one electrode, such as electrically active polymer 122 shown in one option, in Figure 2. Specification page 11, lines 10-28. Assemblies 320, 420, 520 include the rheometric material as shown in Figures 4, 5, 6 and 7. Specification page 12, line 14 to page 13, line 10; page 13, lines 24-28; page 14, line 4 to page 15, line 4; page 15, line 19 to page 17, line 5; and page 17, line 24 to page 19, line 21.

d. Claim 23

The medical device includes a device body, such as lead body 115 shown, for example, in Figure 1. Specification page 10, lines 13-19. The lead body extends from a proximal end to a distal end (e.g., distal end 102 and proximal end 104 shown in Figure 1) and has an intermediate portion 105 therebetween. Specification page 10, lines 3-4. Additional examples of lead bodies 310, 410 and 510 are shown in Figures 4, 5 and 7, respectively. Specification page 13, lines 19-21; page 15, lines 5-15; and page 17, lines 6-19. In another option, the device body includes a guide catheter 600 shown, for instance in Figure 11. Specification page 21, lines 3-18. The medical device includes an electrode, such as electrode assembly 120, used to stiffen the device body (described below), deliver electrical stimulation to tissues and sense electrical activity in tissues. See for instance, Figures 2, and specification page 11, lines 1-9; page 12, lines 1-13; and page 13, lines 11-18. Additional example of electrodes 323, 423 and 523 are shown in Figures 4, 5 and 7, respectively. Specification page 13, line 28 to page 14, line 3; page 15, lines 15-18; and page 17, lines 20-23. Further, the medical device includes rheometric material electrically coupled with the at least one electrode, such as electrically active polymer 122 shown in one option, in Figure 2. Specification page 11, lines 10-28. Assemblies 320, 420, 520 include the rheometric material as shown in Figures 4, 5, 6 and 7. Specification page 12, line 14 to page 13, line 10; page 13, lines 24-28; page 14, line 4 to page 15, line 4; page 15, line 19 to page 17, line 5; and page 17, line 24 to page 19, line 21. The assembly includes a strip of material, such as strip 210, wound around a longitudinal axis of a lead 200, as shown in Figure 3. Specification page 12, line 14 to page 13, line 10.

e. Claim 28

The medical device includes a device body, such as lead body 115 shown, for example, in Figure 1. Specification page 10, lines 13-19. The lead body extends from a proximal end to a distal end (e.g., distal end 102 and proximal end 104 shown in Figure 1) and has an intermediate portion 105 therebetween. Specification page 10, lines 3-4. Additional examples of lead bodies 310, 410 and 510 are shown in Figures 4, 5 and 7,

respectively. Specification page 13, lines 19-21; page 15, lines 5-15; and page 17, lines 6-19. In another option, the device body includes a guide catheter 600 shown, for instance in Figure 11. Specification page 21, lines 3-18. The medical device includes an electrode, such as electrode assembly 120, used to stiffen the device body (described below), deliver electrical stimulation to tissues and sense electrical activity in tissues. See for instance, Figures 2, and specification page 11, lines 1-9; page 12, lines 1-13; and page 13, lines 11-18. Additional example of electrodes 323, 423 and 523 are shown in Figures 4, 5 and 7, respectively. Specification page 13, line 28 to page 14, line 3; page 15, lines 15-18; and page 17, lines 20-23. The medical device includes assemblies, such as assemblies 320, 420 and 520 coupled with the device body, as shown in Figures 4, 5, 6 and 7. Specification page 12, line 14 to page 13, line 10; page 13, lines 24-28; page 14, line 4 to page 15, line 4; page 15, line 19 to page 17, line 5; and page 17, line 24 to page 19, line 21. Further, the medical device includes means for electrically stiffening the at least one assembly and the device body, such as rheometric material including, for instance, strips 210 and assemblies 320, 420 and 520 carrying rheometric material, shown in Figures 4, 5, 6 and 7. Specification page 12, line 14 to page 13, line 10; page 13, lines 24-28; page 14, line 4 to page 15, line 4; page 15, line 19 to page 17, line 5; page 17, line 24 to page 19, line 21; page 21, line 19 to page 22, line 10; and page 22, line 15 to page 25, line 26.

f. Claim 59

The medical device includes a device body, such as lead body 115 shown, for example, in Figure 1. Specification page 10, lines 13-19. The lead body extends from a proximal end to a distal end (e.g., distal end 102 and proximal end 104 shown in Figure 1) and has an intermediate portion 105 therebetween. Specification page 10, lines 3-4. Additional examples of lead bodies 310, 410 and 510 are shown in Figures 4, 5 and 7, respectively. Specification page 13, lines 19-21; page 15, lines 5-15; and page 17, lines 6-19. In another option, the device body includes a guide catheter 600 shown, for instance in Figure 11. Specification page 21, lines 3-18. The medical device includes an electrode, such as electrode assembly 120, used to stiffen the device body (described

below), deliver electrical stimulation to tissues and sense electrical activity in tissues. See for instance, Figures 2, and specification page 11, lines 1-9; page 12, lines 1-13; and page 13, lines 11-18. Additional example of electrodes 323, 423 and 523 are shown in Figures 4, 5 and 7, respectively. Specification page 13, line 28 to page 14, line 3; page 15, lines 15-18; and page 17, lines 20-23. Further, the medical device includes rheometric material that contracts and/or stiffens when electrical current is applied, such as electrically active polymer 122 shown in one option, in Figure 2. Specification page 11, lines 10-28. Assemblies include the electroactive material on segments of the device body. For example, assemblies 320, 342, 344, 420, 460, 462, 464, 466, 520, 560, 562, 564 and 566 are coupled along segments of the device body (e.g., across or adjacent to each other along first surfaces 312, 412, 512 and second surfaces 314, 414, 514). See Figures 4, 5, 6 and 7, respectively. Specification page 13, line 24 to page 15, line 18; page 16, line 14 to page 19, line 21.

g. Claim 65

The medical device includes a device body, such as lead body 115 shown, for example, in Figure 1. Specification page 10, lines 13-19. The lead body extends from a proximal end to a distal end (e.g., distal end 102 and proximal end 104 shown in Figure 1) and has an intermediate portion 105 therebetween. Specification page 10, lines 3-4. Additional examples of lead bodies 310, 410 and 510 are shown in Figures 4, 5 and 7, respectively. Specification page 13, lines 19-21; page 15, lines 5-15; and page 17, lines 6-19. In another option, the device body includes a guide catheter 600 shown, for instance in Figure 11. Specification page 21, lines 3-18. The medical device includes electrodes coupled with the device body, such as electrode assembly 120 having electrodes 124, used to stiffen the device body (described below), deliver electrical stimulation to tissues and sense electrical activity in tissues. See for instance, Figures 2, and specification page 11, lines 1-12; page 12, lines 1-13; and page 13, lines 11-18. Additional examples of electrodes 323, 423 and 523 are shown in Figures 4, 5 and 7, respectively. Specification page 13, line 28 to page 14, line 3; page 15, lines 15-18; and page 17, lines 20-23. Further, the medical device includes rheometric material

electrically coupled with the at least one electrode, such as electrically active polymer 122 shown in one option, in Figure 2. Specification page 11, lines 10-28. Additional examples of rheometric material, such as strips 210; assemblies 320, 420, 520; and electroactive material 618, 714 are shown in Figures 4, 5, 6, 7, 12 and 19, respectively. Specification page 12, line 14 to page 13, line 10; page 13, lines 24-28; page 14, line 4 to page 15, line 4; page 15, line 19 to page 17, line 5; page 17, line 24 to page 19, line 21; page 21, line 19 to page 22, line 10; and page 22, line 15 to page 25, line 26.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

a. Claims 1 and 3-8 are rejected under 35 U.S.C. § 102(e) as being anticipated by Maseda (U.S. Patent No. 6,514,237).

b. Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Lieber et al. (U.S. Patent No. 4,329,993) in view of Maseda (U.S. Patent No. 6,514,237).

7. ARGUMENT

a. The Applicable Law

Establishing Anticipation Under 35U.S.C. § 102

Anticipation under 35 U.S.C. § 102 requires the disclosure in a single prior art reference of each element of the claim under consideration. *See In re Dillon* 919 F.2d 688 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991); *Verdegaal Bros. V. Union Oil Co. of California,* 814 F.2d 628, 631, 2 USPQ 2d 1051, 1053 (Fed. Cir. 1987). It is not enough, however, that the prior art reference discloses all the claimed elements in isolation. Rather, "[a]nticipation requires the presence in a single prior reference disclosure of each and every element of the claimed invention, *arranged as in the claim.*" *Lindemann Maschinenfabrik GmbH v. American Hoist & Derrick Co.*, 730 F.2d 1452, 221 USPQ 481, 485 (Fed. Cir. 1984) (citing *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 220 USPQ 193 (Fed. Cir. 1983)) (Emphasis added). Moreover, "For a prior art reference to anticipate in terms of 35 U.S.C. § 102, every element of the claimed invention must be *identically* shown in a single reference." (Emphasis added). *In re Bond*, 910 F.2d 831 (Fed. Cir. 1990). "The *identical invention* must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989); MPEP § 2131 (Emphasis added).

Furthermore, "[a] functional limitation *must be evaluated and considered*, just like any other limitation of the claim . . . A functional limitation is often used in association with an element . . . to *define a particular capability or purpose that is served by the recited element.*" (Emphasis added). See *In re Swinehart*, 439 F.2d 210, 169 USPQ 226 (CCPA 1971); *In re Caldwell*, 138 USPQ 243 (CCPA 1963); *Lewmar Marine, Inc. v. Barient, Inc.*, 827 F.2d 744, 3 USPQ2d 1766 (Fed. Cir. 1987) ("so that" functional clause of claim renders reference non-anticipating); M.P.E.P. § 2173.05(g),.

Establishing a Prima Facie Case of Obviousness Under 35 U.S.C. § 103

The Examiner has the burden under 35 U.S.C. § 103 to establish a *prima facie* case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 U.S.P.Q.2d 1596, 1598 (Fed. Cir. 1988). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 U.S.P.Q. 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." *In re Wilson*, 424 F.2d 1382, 1385, 165 U.S.P.Q. 494, 496 (CCPA 1970).

In combining prior art references to construct a *prima facie* case, the Examiner must show some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art that would lead an individual to combine the relevant teaching of the references. *Id.* The MPEP contains explicit direction to the Examiner that agrees with the court in *In re Fine*:

> In order for the Examiner to establish a prima facie case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellants's disclosure.

MPEP § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991)).

Analysis of Suggestion to Modify/Combine References under 35 U.S.C. 103

An invention can be obvious even though the suggestion to combine prior art teachings is not found in a specific reference. *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992). At the same time, however, although it is not necessary that the cited references or prior art specifically suggest making the combination, there must be some teaching somewhere which provides the suggestion or motivation to combine prior art teachings and applies that combination to solve the same or similar problem which the claimed invention addresses. One of ordinary skill in the

art will be presumed to know of any such teaching. (See, e.g., *In re Nilssen*, 851 F.2d 1401, 1403, 7 U.S.P.Q.2d 1500, 1502 (Fed. Cir. 1988) and *In re Wood*, 599 F.2d 1032, 1037, 202 U.S.P.Q. 171, 174 (C.C.P.A. 1979)). However, the level of skill is not that of the person who is an innovator but rather that of the person who follows the conventional wisdom in the art. *Standard Oil Co. v. American Cyanamid Co.,* 774 F.2d 448, 474, 227 U.S.P.Q. 293, 298 (Fed. Cir. 1985). Additionally, "the rationale to modify or combine the prior art . . . may be expressly or impliedly contained in the prior art or it may be *reasoned* from knowledge generally available to one of ordinary skill in the art, established scientific principles or legal precedent." (Emphasis added). *In re Fine,* 837 F.2d 1071 (Fed. Cir. 1988), M.P.E.P. § 2144.

According to *In re Sang Su Lee*, "there must be some motivation, suggestion, or teaching of the desirability of making the specific combination that was made by the Appellants." *In re Sang Su Lee*, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002), *citing In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988). The mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990); MPEP § 2143.01. Furthermore, the "factual question of motivation is material to patentability, and could *not* be resolved on *subjective belief and unknown authority.*" (Emphasis added). *In re Sang Su Lee*, 61 U.S.P.Q.2d 1430 (Fed. Cir. 2002). A showing of a suggestion, teaching, or motivation to combine prior teachings "must be clear and particular . . . Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *In re Dembiczak*, 175 F.2d 994, 50 U.S.P.Q.2d 1614 (Fed. Cir. 1999).

Invention as a Whole Must be Considered under 35 U.S.C. 103

The test for obviousness under § 103 must take into consideration the invention as a whole; that is, one must consider the particular problem solved by the combination of elements that define the invention. *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 U.S.P.Q. 543, 551 (Fed. Cir. 1985). In determining the differences between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the

differences *themselves* would have been obvious, but whether the claimed invention *as a whole* would have been obvious. (Emphasis in original). *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Schenck v. Nortron Corp.*, 713 F.2d 782, 218 USPQ 698 (Fed. Cir. 1983); *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143, 227 USPQ 543, 551 (Fed. Cir. 1985); MPEP § 2141.02. The Examiner can only rely on references which are either in the same field as that of the invention, or if not in the same field, must be "reasonably pertinent to the particular problem with which the inventor was concerned." *MPEP* § 2141.01 (a) (citing *In re Oetiker*, 24 U.S.P.Q.2d 1443 at 1445). The Examiner must also recognize and consider not only the similarities but also the critical differences between the claimed invention and the prior art. *In re Bond*, 910 F.2d 831, 834, 15 U.S.P.Q.2d 1566, 1568 (Fed. Cir. 1990), reh'g denied, 1990 U.S. App. LEXIS 19971 (Fed. Cir. 1990). For instance, the reference must be considered as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 369 U.S. 851 (1984); MPEP 2141.02. Finally, the Examiner must avoid hindsight. *In re Bond*, 910 F.2d 831, 834, 15 U.S.P.Q.2d 1566, 1568 (Fed. Cir. 1990), reh'g denied, 1990 U.S. App. LEXIS 19971 (Fed. Cir. 1990). The Examiner cannot use the Appellants's structure as a "template" and simply select elements from the references to reconstruct the claimed invention. *In re Gorman*, 933 F.2d 982, 987, 18 U.S.P.Q.2d 1885, 1888 (Fed. Cir. 1991). Furthermore, the teachings of the prior art references are not sufficient to render the claims *prima facie* obvious if modifying or combining the references would change of the principle of operation of the prior art invention being modified. *In re Ratti*, 270 F.2d 810 (CCPA 1959); MPEP § 2143.01.

All elements of the Claims must be Considered during Examination

The United States Supreme Court expressly stated and made clear that "[e]ach element contained in a patent claim is deemed material to defining the scope of the patented invention." *Warner-Jenkinson Co., Inc. v. Hilton Davis Chem. Co.*,520 U.S. 17, 29, 117 S. Ct. 1040, 1049, 137 L.Ed.2d 146, 161, 41 U.S.P.Q.2d 1865, 1871 (1997). Each claim must be read in view of the specification of which it is a part, and in view of

the other claims. *In re Marosi, Stabenow, and Schwarzmann*, 218 U.S.P.Q. 289, 292 (Fed. Cir. 1983). The use of hindsight to modify or extend the teachings of a reference to the claimed invention is improper, and may not be used as the basis for rejection. *In re Sang Su Lee*, 61 U.S.P.Q.2d 1430, 1433 (Fed. Cir. 2002).

b. Discussion of the Rejections of Claims 1, 3-10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-69

i. Claims 1, 3-6 and 8 were improperly rejected under 35 U.S.C. § 102(e) as being unpatentable over Maseda (U.S. 6,514,237), hereinafter Maseda.

Appellants respectfully submit that the rejections of claims 1, 3-6 and 8 under 35 U.S.C. § 102(e) are improper. Reconsideration and allowance of claims 1, 3-6 and 8 are respectfully requested.

(a) The Rejections of Claims 1, 3-6 and 8 Fail to Provide a Proper Case of Anticipation Because Maseda Does Not Identically Teach Each of the Elements Claimed.

The rejections of claims 1, 3-6 and 8 fail to state a proper case of anticipation because Maseda does not identically show each of the claimed elements, as required by *In re Bond*. Further, the rejections of claims 1, 3-6 and 8 fail to state a proper case of anticipation because Maseda does not show the identical invention in as complete detail as is contained in the claim, pursuant to *Richardson v. Suzuki Motor Co.* Appellants can not find, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. Claims 3-6 and 8 depend from claim 1 and thereby include all of its limitations. The Final Office Action fails to show in Maseda where there is such teaching, and merely states at page 2, section 3, "the examiner considers the conductive platinum metal discussed in col. 5, lines 1-19 to constitute at least one electrode . . . Platinum is considered to be capable of transmitting and receiving electrical signals to

and from tissue due to its conductive and biocompatible nature." Appellants respectfully traverse this conclusory statement in so far as it fails to properly characterize the teaching of Maseda. Appellants can not find in Maseda, for instance, at least one electrode configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. In contrast to the statements in the Final Office Action, the only reference in Maseda to an electrode states:

> Ion-exchange polymer-noble metal composites are manufactured utilizing a chemical process in which a noble metal is deposited within the molecular network of the base ionic polymer. Metal ions, for example, platinum are dispersed throughout the hydrophilic regions of the polymer and subsequently chemically reduced to the corresponding metal atoms. This process results in the formation of dendritic-type electrodes. When an external voltage of approximately 2 volts or higher is applied to an ion-exchange polymer-noble metal composite film, it bends toward the anode. An increase in the applied voltage, up to a predetermined limit, causes a larger bending displacement. When the polarity of the voltage is changed, the film undergoes a swinging movement. The displacement of the film not only depends on the magnitude of the applied voltage, but also on the frequency of the applied voltage. Lower frequencies lead to higher displacements. Accordingly, the movement of the film or strip may be fully controllable by controlling the applied voltage.

Maseda, column 5, lines 1-19. Appellants respectfully submit the preceding quotation is the only teaching for an electrode in Maseda and does not appear to teach the *identical invention in as complete detail* as is contained in claim 1.

Further, in the response dated December 5, 2005, Appellants requested the Examiner show where in Maseda there is teaching for at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1, and incorporated in claims 3-6 and 8. The Advisory Action dated January 9, 2006 failed to address this deficiency in teaching. Instead, the Advisory Action merely stated at page 3, "The electrode disclosed in the prior art reference is *substantially equivalent* to that disclosed by applicant and *capable of operating in the manner claimed*." (Emphasis added). Appellants respectfully disagree that 'substantial equivalence' or 'capability of operating in the manner claimed' are the proper standards for determining anticipation according to 35 USC § 102. In

contrast, because Maseda does not *identically* show each of the claimed elements, Maseda does not anticipate claim 1 or dependant claims 3-6 and 8. Moreover, absent such a showing, Appellants assert the Final Office Action and Advisory Action appear to rely on personal knowledge in making these statements. Pursuant to 37 C.F.R. § 1.104(d)(2), Appellants traversed these statements in the response dated December 5, 2005, herein traverse these statements again and respectfully requests the Examiner submit an affidavit providing support for the assertion with the next Office Communication or withdraw this line of argument.

The Final Office Action fails to provide a proper case of anticipation because Maseda does not show the identical invention in as complete detail as is contained in the claims. Reconsideration and allowance of claims 1, 3-6 and 8 are respectfully requested.

(b) The Rejections of Claims 1, 3-6 and 8 Fail to Provide a Proper Case of Anticipation Because the Final Office Action Fails to Give Patentable Weight to Functional Limitations.

The rejections of claims 1, 3-6 and 8 fail to state a proper case of anticipation because the Final Office Action fails to consider functional limitations in the claims, as required by *In re Swinehart* and *Lewmar Marine, Inc. v. Barient, Inc.* Appellants respectfully traverse the statements in the Final Office Action at page 5, first paragraph, "The examiner cannot find in the claim where it is stated that the electrode must perform transmission and reception of electrical signals to and from tissue. The examiner cannot find any structure in the claim for generating such signals and sensing such signals." The Final Office Action refuses to give patentable weight to at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1. Claims 3-6 and 8 depend from claim 1 and thereby include all of its limitations. As stated above, Appellants can not find in Maseda, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1 and incorporated in dependent

claims 3-6 and 8. Reconsideration and allowance of claims 1, 3-6 and 8 are respectfully requested.

(c) The Rejections of Claims 1, 3-6 and 8 Fail to Provide a Proper Case of Anticipation Because the Final Office Action Fails to Establish a *Prima Facie* Case of Inherency.

The rejections of claims 1, 3-6 and 8 fail to state a proper case of anticipation because the Final Office Action fails to provide a *prima facie* case of inherency, as required by *Continental Can Co. v. Monsanto Co.* and *Ex parte Levy.* Appellants respectfully traverse the Final Office Action statement at page 5, first paragraph, "Platinum electrodes are *inherently* capable of transmitting and receiving electrical signals to and from the body due to their conductive and biocompatible nature." (Emphasis added). Appellants respectfully submit that the Final Office Action has not produced extrinsic evidence to show that at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1 is *necessarily present* in Maseda, as required by *Continental Can Co. v. Monsanto Co.* Further the Final Office Action has not provided a *prima facie* showing of technical reasoning, as required by *Ex parte Levy,* to support the conclusory statement at page 5, first paragraph of the Final Office Action that, "the platinum electrode of Maseda is thus capable of transmitting and receiving electrical signals to and from tissue." Instead, the Final Office Action merely argues that "the platinum electrode of Maseda can be attached to the outer tubular body 114 enabling it to come into contact with tissue or conductive body fluids." Final Office Action, page 5, first paragraph. Appellants thereby respectfully submit the Final Office Action fails to provide technical reasoning showing that the allegedly inherent characteristic *necessarily flows* from the teachings of Maseda, as required by *Ex parte Levy.* As stated above, Appellants can not find in Maseda, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claim 1 and incorporated in dependent

claims 3-6 and 8. Reconsideration and allowance of claims 1, 3-6 and 8 are respectfully requested.

ii. Claim 7 was improperly rejected under 35 U.S.C. § 102(e) as being unpatentable over Maseda (U.S. 6,514,237).

Appellants respectfully submit that the rejection of claim 7 under 35 U.S.C. § 102(e) is improper. The Rejection of Claim 7 Fails to Provide a Proper Case of Anticipation Because Maseda Does Not Identically Teach the Element Claimed.

The rejection of claim 7 fails to state a proper case of anticipation because Maseda does not identically show each of the claimed elements, as required by *In re Bond*. Appellants can not find, for example, the device body comprising an elongate lead body configured to be coupled with a pulse generator, as recited in claim 7. Moreover, Appellants respectfully traverse the Final Office Action statement at page 3, first full paragraph, "The fact that the electroactive material at the distal end of the device body must be connected to a power supply at the proximal end as per col. 5, lines 40-55 dicates that the lead body be configured to be coupled to a pulse generator." Appellants respectfully traverse this conclusory statement in so far as it fails to properly characterize the teaching of Maseda. Instead, Maseda merely states at column 5, lines 41-43, "The control module 300 preferably comprises a power supply capable of supplying both DC voltage/current and AC voltage/current at various frequencies." Appellants respectfully submit the preceding quotation from Maseda does not appear to teach the *identical invention in as complete detail* as is contained in claim 7, and required by *In re Bond* and *Richardson v. Suzuki Motor Co.* Moreover, absent such a showing, Appellants assert the Final Office Action appears to rely on personal knowledge in making these statements. Pursuant to 37 C.F.R. § 1.104(d)(2), Appellants traversed these statements in the response dated December 5, 2005, herein traverse these statements again and respectfully requests the Examiner submit an affidavit providing support for the assertion with the next Office Communication or withdraw this line of argument.

Further, Appellants respectfully submit claim 7 is patentable at least as a dependent claim of patentable base claim 1, and the discussion for claim 1 above is repeated in support of claim 7.

The Final Office Action fails to provide a proper case of anticipation because Maseda does not show the identical invention in as complete detail as is contained in claim 7. Reconsideration and allowance of claim 7 are respectfully requested.

iii. Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 were improperly rejected under 35 U.S.C. 103 as being unpatentable over Lieber et al. (U.S. 4,329,993), hereinafter Lieber, in view of Maseda (U.S. Patent no. 6,514,237). .

Appellants respectfully submit that the rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 under 35 U.S.C. 103 are improper. Reconsideration and allowance of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 are respectfully requested.

(a) The Rejections of Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 Fail to Maintain a *Prima Facie* Case of Obviousness Because Combining Maseda and Lieber In the Proposed Manner Would Impermissibly Change the Principle of Operation of Lieber.

The rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 fail to maintain a *prima facie* case of obviousness because, among other reasons, combining Maseda with Lieber in the proposed manner would change the principle of operation of Lieber. According to *In re Ratti*, because the principle of operation of Lieber would be changed, the proposed combination is insufficient to render the claims *prima facie* obvious. Appellants respectfully submit Lieber states at column 3, lines 52-64, "In use, the soft, pliable catheter body . . . is advanced, with the balloon in deflated or only partially inflated condition, into the right atrium 12. The balloon is then inflated to its maximum recommended capacity and the *flow of blood through the heart rapidly propels*

the inflated balloon-tipped catheter from the right atrium into the pulmonary artery 18 (FIG. 1). It will be observed that when the catheter is so positioned, *balloon 26 has advanced through the pulmonary artery* into . . . the pulmonary capillary position." (Emphasis added). In contrast, Maseda recites in the abstract, for example, "an intralumen medical device which *incorporates electroactive polymer actuators* into various sections of flexible medical probes *results in a device capable of precisely navigating through tortuous passageways*." Appellants respectfully submit that by exchanging the inflated balloon mechanism of Lieber with the electroactive polymer actuators of Maseda the principle of operation for navigating the vasculature of Lieber is impermissibly changed, and according to *In re Ratti*, the proposed combination is thereby insufficient to render claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 *prima facie* obvious. Reconsideration and allowance of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 are respectfully requested.

(b) The Rejections of Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 Fail to State a *Prima Facie* Case of Obviousness Because There is No Objective Reason to Combine Lieber with Maseda.

Further, the rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 fail because the Final Office Action does not identify a proper motivation to combine Lieber with Maseda. Pursuant to *In re Mills*, the mere fact that references *can* be combined does not render the resultant combination obvious unless prior art also suggests (i.e. a prior art supported objective suggestion) the desirability of the combination. The Final Office Action does not state how Maseda would be in need of, for example, at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue, as recited in claims 9, 23, 28, 59 and 65 and incorporated in dependent claims 10, 12-14, 16, 21, 22, 26, 29, 33, 58, 60-64 and 66-68. Appellants can not find any objective suggestion in Maseda to employ such structure. As required by *In re Mills*, Appellants respectfully request the Examiner

identify an objective source for the motivation to combine Lieber with Maseda in the manner proposed.

Further, Appellants respectfully traverse the Final Office Action statements at page 3, last paragraph, "Maseda, however, teaches that the use of such an assembly on a wide range of medical devices including the type disclosed by Lieber et al. is advantageous from the standpoint of increasing flexibility and steerability of the catheter as it is introduced into the body. Increased maneuverability through the tortuous vasculature system, high precision, and ease of placement – very important design considerations for the medical artisan – make the incorporation of the Maseda assembly and related control system on the medical device of Lieber et al. an obvious choice." Further still, Appellants traverse the Advisory Action statement at page 2, "the teachings of Maseda are clearly generic to any medical device requiring controlled placement within the body." Appellants traverse these statements from the Final Office Action and Advisory Action in so far as Maseda is not applicable to references, such as Lieber, that teach a contrary mechanism with a different principle of operation for maneuvering through vasculature, as described above. Because combining Maseda with Lieber would change the principle of operation for Lieber, as described above, and a proper objective suggestion for combining Lieber with Maseda has not been provided, Appellants respectfully submit a *prima facie* case of obviousness has not been established. Reconsideration and allowance of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 are respectfully requested.

(c) The Rejections of Claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 Fail to State a *Prima Facie* Case of Obviousness Because The Final Office Action Does Not Consider the Claims as a Whole.

Further still, the rejections of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 fail because the rejections do not consider the claims as a whole. Instead, the Final Office Action seizes upon the differences of the claims and argues the differences would be obvious instead of considering the claims as a whole, as required by *Interconnect Planning Corp. v. Feil.* For example, the Final Office Action at page 3, last paragraph

states, "Lieber et al. disclose a medical device comprising an elongate device body and at least one electrode 35 coupled thereto for stimulating and sensing. Lieber et al., however, do not disclose the use of an assembly coupled with the device body including a rheometric material that contracts and/or stiffens when electrical current is applied thereto. Maseda, however, teach that the use of such an assembly on a wide range of medical devices including the type disclosed by Lieber et al. is advantageous." In contrast, claim 9 recites that the medical device includes, *in combination with all of the elements of claim 9,* at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when electrical current is applied thereto. Additionally, claim 23 recites that the medical device includes, *in combination with all of the elements of claim 23,* at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when current is applied thereto. Further, claim 28 recites that the medical device includes, *in combination with all of the elements of claim 23*, means for electrically stiffening the at least one assembly and the device body, wherein electrical current is applied to the at least one assembly. Further still, claim 59 recites that the medical device includes, *in combination with all of the elements of claim 59*, the first assembly and the second assembly including a rheometric material, and the rheometric material of at least one of the first assembly and the second assembly contracts and/or stiffens when electrical current is applied thereto. Moreover, claim 65 recites that the medical device includes, *in combination with all of the elements of claim 65,* a rheometric material electrically coupled with the second electrode, the rheometric material contracts and/or stiffens when electrical current is applied thereto. As described above, the Final Office Action fails to show teaching or objective suggestion for this new combination that overcomes the deficiencies previously described in sections (a) and (b). Instead, the Final Office Action merely states the differences of the claims with respect to the prior art are obvious without focusing on the claims as a whole. Because the rejection focuses upon the differences of the claims and not the claims as a whole, a proper *prima facie* case of obviousness has not been established.

Moreover, by failing to consider the invention as a whole, the Final Office Action uses Appellants' disclosure as a template and performs improper hindsight reconstruction to selectively pick and choose elements from Maseda and Lieber in the proposed manner. See *In re Gorman*. According to *In re Vaeck*, the teaching or suggestion to make the claimed device must be found in the prior art, not in the Appellants' disclosure.

Because the Final Office Action fails to consider the claims as a whole and performs hindsight reconstruction using Appellants' disclosure as a template, Appellants respectfully submit a proper *prima facie* case of obviousness has not been established. Reconsideration and allowance of claims 9, 10, 12-14, 16, 21-23, 26, 28, 29, 33 and 58-68 are respectfully requested.

8. SUMMARY

The Final Office Action fails to establish a case of anticipation because Maseda does not identically teach each of the claimed elements. Further, the Final Office Action fails to establish a legally sufficient case of obviousness and Appellants traverse on several grounds as described in detail above. Appellants note that combining Lieber with Maseda as proposed would impermissibly change the principle of operation of Lieber. Further, the Final Office Action fails to provide a proper objective suggestion to combine Lieber with Maseda. The Final Office Action focuses upon the differences of the claims as opposed to the claims as a whole, and instead relies on Appellants' disclosure in hindsight to selectively choose elements from each reference for the proposed combination.

It is respectfully submitted that the art cited does not render the claims anticipated or obvious and that the claims are patentable over the cited art. Reversal of the rejections and allowance of the pending claims are respectfully requested.

Respectfully submitted,

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By their Representatives,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Appeal Brief-Patents, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 17 day of April, 2006.

Paula Suchy
Name

Paula Suchy
Signature

CLAIMS APPENDIX

1. (Rejected) A medical device comprising:

a device body extending from a proximal end to a distal end;

at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue; and

a rheometric material electrically coupled with the at least one electrode, the rheometric material contracts and/or stiffens when electrical current is applied thereto.

2. (Withdrawn) The medical device as recited in claim 1, wherein the rheometric material comprises a coating of electroactive polymer having a thickness of about 180 micron.

3. (Rejected) The medical device as recited in claim 1, wherein the rheometric material comprises a strip of material wound around a longitudinal axis of the device body.

4. (Rejected) The medical device as recited in claim 1, wherein the rheometric material comprises a layer of material on an outer surface of the at least one electrode.

5. (Rejected) The medical device as recited in claim 1, wherein the device body is defined by a first surface and a second surface, and the at least one electrode is disposed on the first surface of the device body.

6. (Rejected) The medical device as recited in claim 5, wherein the first surface is opposite the second surface, and at least one electrode is disposed on the second surface of the device body.

7. (Rejected) The medical device as recited in claim 1, wherein the device body comprises an elongate lead body configured to be coupled with a pulse generator.

8. (Rejected) The medical device as recited in claim 1, wherein the rheometric material comprises an electroactive polymer.

9. (Rejected) A medical device comprising:

an elongate device body extending from a proximal end to a distal end;

at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue;

at least one assembly coupled with the device body, where the at least one assembly is configured to stiffen the device body; and

the at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when electrical current is applied thereto.

10. (Rejected) The medical device as recited in claim 9, further comprising a control system which selectively applies current to the rheometric material, and a means for providing feedback to the control system.

11. (Withdrawn) The medical device as recited in claim 9, further comprising a means for transferring fluid along the elongate device body.

12. (Rejected) The medical device as recited in claim 9, wherein the device body is defined by a first outer surface and a second outer surface, and the at least one assembly is disposed on the first outer surface of the device body.

13. (Rejected) The medical device as recited in claim 12, wherein the first outer surface is opposite the second outer surface.

14. (Rejected) The medical device as recited in claim 9, wherein a plurality of assemblies are disposed on a first outer surface of the device body.

15. (Withdrawn) The medical device as recited in claim 9, wherein the device body includes a first outer surface and a second outer surface, and a plurality of assemblies are disposed on the first outer surface, and a plurality of assemblies are disposed on the second outer surface.

16. (Rejected) The medical device as recited in claim 9, wherein the at least one assembly is disposed adjacent to the distal end of the device body.

17. (Withdrawn) The medical device as recited in claim 9, wherein the assembly is disposed within at least one lumen of the device body along at least a portion of a length of the device body.

18. (Withdrawn) The medical device as recited in claim 17, wherein at least one assembly is disposed along the entire length of the device body.

19. (Withdrawn) The medical device as recited in claim 17, wherein the device body includes two or more lumens therein, and at least one lumen has a different cross-section than another lumen, and rheometric material is disposed within the two or more lumens.

20. (Withdrawn) The medical device as recited in claim 9, wherein the rheometric material comprises magnoactive material.

21. (Rejected) The medical device as recited in claim 9, wherein the rheometric material comprises electroactive material.

22. (Rejected) The medical device as recited in claim 9, wherein the device body has a preformed curved length portion.

23. (Rejected) A medical device comprising:

a device body extending from a proximal end to a distal end;

at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue;

at least one assembly coupled with the device body, the at least one assembly includes at least one winding of material wound around a longitudinal axis of the device body, where the at least one assembly is configured to stiffen the device body; and

the at least one assembly including a rheometric material, the rheometric material contracts and/or stiffens when current is applied thereto.

24. (Withdrawn) The medical device as recited in claim 23, wherein the rheometric material is an electroactive polymer coating of about 180 micron in thickness.

25. (Withdrawn) The medical device as recited in claim 23, wherein the winding of material extends from the proximal end to the distal end of the device body.

26. (Rejected) The medical device as recited in claim 23, further comprising a control system which selectively applies current to the electroactive material, and a means for providing feedback to the control system.

27. (Withdrawn) The medical device as recited in claim 23, wherein the winding of material is disposed within one or more lumens of the device body.

28. (Rejected) A medical device comprising:

an elongate device body extending from a proximal end to a distal end;

at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue;

at least one assembly coupled with the device body; and

means for electrically stiffening the at least one assembly and the device body, wherein electrical current is applied to the at least one assembly.

29. (Rejected) The medical device as recited in claim 28, wherein the at least one assembly includes an electroactive polymer associated therewith.

30. (Withdrawn) The medical device as recited in claim 28, wherein the at least one assembly includes magnoactive material associated therewith.

31. (Withdrawn) The medical device as recited in claim 28, wherein the device body includes at least one lumen therein, and rheometric material is disposed within one or more lumens.

32. (Withdrawn) The medical device as recited in claim 31, wherein the device body further includes at least one lumen configured to receive a medical instrument or fluid therethrough.

33. (Rejected) The medical device as recited in claim 28, wherein the device body has a preformed curve.

34. (Withdrawn) A medical device comprising:

an elongate device body extending from a proximal end to a distal end;

the device body including at least one lumen therein, and rheometric material is disposed within one or more lumens, the rheometric material configured to stiffen the elongate device body upon application of electrical energy to the rheometric material.

35. (Withdrawn) The medical device as recited in claim 34, wherein the rheometric material includes an electroactive polymer.

36. (Withdrawn) The medical device as recited in claim 34, wherein the rheometric material includes magnoactive material.

37. (Withdrawn) The medical device as recited in claim 34, wherein the device body includes a passage extending from the proximal end to the distal end, the passage sized to receive at least one instrument therein, and a plurality of lumens are disposed about the passage.

38-57. (Cancelled)

58. (Rejected) The medical device as recited in claim 14, wherein the plurality of assemblies includes at least a first assembly coupled with a first segment of the device body and a second assembly coupled with a second segment of the device body.

59. (Rejected) A medical device comprising:

an elongate device body extending from a proximal end to a distal end;

at least one electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue;

a first assembly coupled with a first segment of the device body, where the first assembly is configured to stiffen the first segment of the device body;

a second assembly coupled with a second segment of the device body, where the second assembly is configured to stiffen the second segment of the device body; and

the first assembly and the second assembly include a rheometric material, and the rheometric material of at least one of the first assembly and the second assembly contracts and/or stiffens when electrical current is applied thereto.

60. (Rejected)The medical device of claim 59, further comprising a control system which selectively applies current to at least one of the first assembly and the second assembly, and a means for providing feedback to the control system.

61. (Rejected) The medical device of claim 59, wherein at least one of the first segment and the second segment is stiff when electrical current is applied to the rheometric material.

62. (Rejected) The medical device of claim 61, wherein one of the first segment and the second segment is stiff when electrical current is applied to the rheometric material, and the other of the first segment and the second segment is relaxed.

63. (Rejected) The medical device of claim 59, wherein the rheometric material comprises a layer of material on an outer surface of the at least one electrode.

64. (Rejected) The medical device of claim 59, wherein the first assembly and the second assembly are disposed on a first outer surface of the device body.

65. (Rejected) A medical device comprising:

a device body extending from a proximal end to a distal end;

a first electrode coupled with the device body, where the at least one electrode is configured to transmit and receive electrical signals to and from tissue;

a second electrode coupled with the device body;

a rheometric material electrically coupled with the second electrode, the rheometric material contracts and/or stiffens when electrical current is applied thereto.

66. (Rejected) The medical device of claim 65, wherein the first electrode and the second electrode are electrically coupled.

67. (Rejected) The medical device of claim 65, wherein the rheometric material comprises a layer of material on an outer surface of at least the second electrode.

68. (Rejected) The medical device of claim 65, wherein the device body comprises an elongate lead body configured to be coupled with a pulse generator.

69. (Rejected) The medical device of claim 65, wherein the rheometric material includes an electroactive material.

EVIDENCE APPENDIX

Office Action dated August 24, 2004

Final Office Action dated October 5, 2005

Response dated December 5, 2005

Advisory Action dated January 9, 2006

U.S. 6,514,237 entered in the Office Action dated August 24, 2004

U.S. 4,329,993 entered in the Office Action dated October 5, 2005

RELATED PROCEEDINGS APPENDIX

None.